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POOLED ANALYSIS OF LONG-TERM SAFETY DATA FROM THE RESOLUTE CLINICAL TRIAL PROGRAM

i2 Poster Contributions
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Background: Analysis of large pooled datasets provides a more accurate assessment of rare serious adverse events following treatment of coronary artery disease with drug-eluting stents. Very late stent thrombosis (VLST, ≥1 yr post-procedure) is of particular concern given the potential for serious clinical consequences such as cardiac death, myocardial infarction (MI) or clinically-driven target lesion revascularization (TLR). The RESOLUTE clinical trials were conducted using similar definitions and adjudication procedures allowing analysis of pooled clinical endpoints.

Methods: Two year follow-up data was pooled for 5,130 patients treated with the Resolute zotarolimus-eluting stent (R-ZES) on one randomized (RESOLUTE All Comers [R-AC], N = 1140) and four single arm trials (RESOLUTE, (N = 139); RESOLUTE US [R-US], (N = 1402); RESOLUTE International [R-Int], (N = 2349); RESOLUTE Japan [R-Japan], (N = 100)). Pooled safety endpoints (cardiac death, myocardial infarction [MI], and VLST) for R-ZES patients were compared with safety endpoints for patients receiving the everolimus-eluting stent (EES) from Resolute All Comers. All RESOLUTE trials recommended six months dual antiplatelet therapy (DAPT). Propensity scores were calculated to adjust for differences in baseline patient and lesion characteristics.

Results: Data from RESOLUTE, R-AC, and R-Int available at two years showed the cumulative frequency of ST was 1.0% for R-ZES and EES (adjusted hazard ratio 1.43; p=0.32) and VLST was 0.2% for R-ZES and 0.3% for EES (adjusted hazard ratio 0.908; p=0.906). DAPT compliance dropped from 89.3% at 1 yr to 35.4% at 2 years for R-ZES patients and from 83.8% to 18.1% for EES patients. The cumulative incidence of cardiac death or MI (R-ZES 5.5%, EES 6.2%, p = .52), and TLR (R-ZES 4.8%, EES 5.2%, p = .98) were similar for patients receiving the R-ZES and the EES.

Conclusions: Pooled data analysis confirms a low rate of ST and VLST through 2 years for R-ZES. Two year rates of cardiac death or MI and TLR in patients treated with R-ZES are similar to EES. Complete 2 year follow-up data, now including R-US and R-Japan patients, will be analyzed and presented.